

Product Name: MILBEMAX TABLETS FOR DOGS
APVMA Approval No: 54266/127957



Label Name:	MILBEMAX TABLETS FOR DOGS
Signal Headings:	CAUTION KEEP OUT OF REACH OF CHILDREN FOR ANIMAL TREATMENT ONLY
Constituent Statements:	125 mg/Tb PRAZIQUANTEL 12.5 mg/Tb MILBEMYCIN OXIME
Claims:	<p>For the treatment and control of roundworm, whipworm, hookworm and tapeworm, and the prevention of heartworm in dogs.</p> <p>Recommended for dogs over 5 kg body weight.</p> <p>For:</p> <ul style="list-style-type: none">• Treatment and control of roundworm (<i>Toxocara canis</i>, <i>Toxascaris leonina</i>)• Treatment and control of whipworm (<i>Trichuris vulpis</i>)• Treatment and control of hookworm (<i>Ancylostoma caninum</i>, <i>Ancylostoma braziliense</i>)• Treatment and control of tapeworm infections (<i>Dipylidium caninum</i>, <i>Taenia</i> spp., <i>Echinococcus granulosus</i>)• Prevention of heartworm (<i>Dirofilaria immitis</i>)
Net Contents:	6, 10, 20, 50, 100 Tablets
Directions for Use:	
Restraints:	
Contraindications:	
Precautions:	For heartworm prevention, the tablet(s) must be administered every month. If you miss the 30-day interval by no more than 7 days, administer MILBEMAX Tablets immediately and resume your monthly dosing schedule. If the interval is longer than 7 days, consult your veterinarian before recommencing MILBEMAX Tablets dosing schedule.

Side Effects:	
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Dosage and Administration:	<p>Consult a veterinarian before use. Before starting MILBEMAX, you should have your veterinarian confirm, by a simple test, that your dog does not have heartworm.</p> <p>MILBEMAX Tablets should be given by mouth. The minimum dose is 0.5 mg milbemycin oxime and 5 mg praziquantel per kg body weight.</p> <p>(dosage table) For dogs > 5 kg, MILBEMAX Tablets for Dogs should be used. For dogs > 50 kg, a combination of tablets should be given, consistent with the recommended minimum dose.</p> <p>For control of gastrointestinal worms: MILBEMAX Tablets for Small Dogs and Puppies should be administered orally to puppies at 2, 4, 8 and 12 weeks of age, then every 3 months. MILBEMAX Tablets for dogs should be administered to dogs weighing over 5 kg. For puppies, use MILBEMAX Tablets for Small Dogs and Puppies. Nursing bitches should be treated at the same time as their puppies. Adult dogs should be treated every 3 months. If worm problems persist, consult a veterinarian. Pregnant bitches should be treated at mating, then 10 days before whelping, then at the same times as puppies. In hydatid tapeworm areas, dogs should be dosed monthly or on veterinary advice.</p> <p>For heartworm prevention: MILBEMAX Tablets must be administered orally every month, preferably on the same date each month. If MILBEMAX Tablets replace daily dosing heartworm tablets containing DEC (Diethylcarbamazine citrate), the first dose must be given within 30 days of the changeover. Growing pups may gain sufficient weight during the course of treatment to require an increased dose of MILBEMAX Tablets. MILBEMAX Tablets may be hidden in food, or the dog dosed directly. When administering MILBEMAX Tablets, be certain that the entire dose is consumed. The dog should be watched for several minutes following dosing to be sure that all tablet(s) have been eaten. If all the medicine is not eaten, redose as soon as possible, with the full dose. This section contains file attachment.</p>
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General Directions:	<p>MILBEMAX Tablets provide a wide margin of safety in dogs when used according to label directions. The active ingredient, milbemycin oxime, has been tested in over 75 different breeds of dogs, including pregnant females, breeding males and females, and puppies over 2 weeks old. Satisfactory margins of safety have been demonstrated for both milbemycin oxime and praziquantel when administered during all reproductive phases. Some mild, transient, shock-like reactions have occurred when treating dogs carrying a high number of microfilariae at the time of the first treatment with MILBEMAX Tablets. Contact your veterinarian if any unusual signs develop following treatment with MILBEMAX Tablets. This formulation is not suitable for use in cats.</p> <p>INTESTINAL PARASITES Hookworms, roundworms, whipworms and tapeworms are common intestinal parasites of dogs in most parts of Australia. Puppies can acquire hookworm infections through their mother's milk, and dogs can acquire hookworm infections from infective larvae that accumulate in their environment, by ingestion and/or penetration through the skin. Hookworms are bloodsucking parasites of</p>
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the small intestine. Hookworm infections can cause anaemia, bloody diarrhoea and even death if blood loss is severe.

Roundworm infections can be acquired prior to birth, through the mother's milk, and by ingestion of eggs from faeces. Roundworms commonly cause general debilitation, which may be manifested by a dull hair coat, failure to thrive, abdominal discomfort, a pot-bellied appearance, vomiting and diarrhoea. Roundworms can occasionally pre-dispose puppies to lung infections. The large worms fill the small intestines and interfere with the absorption of nutrients. Rarely, severe infections can be fatal due to obstruction of the intestine by impacted worms.

Adult whipworms reside in the large intestine causing inflammation of the intestinal lining. This inflammation can cause diarrhoea, with or without blood.

Hydatid tapeworm poses a severe risk to human health by transmission to humans from infected dogs. In hydatid tapeworm areas, dogs should be dosed monthly or on veterinary advice, to ensure that newly acquired hydatid tapeworms are expelled before reaching maturity. **DO NOT FEED THE DOG OFFAL OR ALLOW ACCESS TO OFFAL FROM ANY SOURCE.** Ensuring this will help break the life cycle of the hydatid tapeworm. The most common tapeworm is *Dipylidium caninum*, transmitted by fleas. The life cycle is 3 weeks, and it is possible for the dog to become reinfected and shed worm segments between monthly doses. Flea control is recommended.

HEARTWORM DISEASE IN DOGS

Heartworm disease is a serious problem in dogs and can cause death. Much of the damage occurs before there are any outward signs of the disease. Prevention is the key. The disease is caused by large round bodied worms (*Dirofilaria immitis*). A dog not receiving preventative medication can be infected with as many as several hundred worms. The adult worms are large (females up to 35 cm, males up to 17 cm) and cause disease by interfering with the function of the right side of the heart and major blood vessels leading from it. Other organs can progressively become involved because of reduced blood flow, sometimes leading to death.

Many dog owners are not aware that their dog is sick until quite late in the disease process. Signs include coughing, laboured breathing, listlessness, a swollen abdomen and loss of condition.

It is possible to treat dogs with heartworm disease, however early detection and prompt treatment is important. If the disease is allowed to progress to the advanced state, treatment is more difficult, the risk to dogs is greater and some permanent irreversible damage may have taken place. The best way to control heartworm disease is to prevent it.

Withholding Periods:	
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Trade Advice:	
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Safety Directions:	
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First Aid Instructions:	If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 1126. If in eyes, hold eyes open, flood with water for at least 15 minutes and see a doctor.
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First Aid Warnings:	
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Additional User Safety:	
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Environmental Statements:	
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Disposal:	Dispose of empty containers by wrapping in paper and putting in garbage.
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Storage:	Store below 25 °C (air conditioning).
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MILBEMAX TABLETS FOR DOGS AND SMALL DOGS (APVMA# 54266, 59225)
Recommended Dosing Schedule Table

Body weight (kg)	MILBEMAX Tablets for Small Dogs and Puppies	MILBEMAX Tablets for Dogs
0.5 - 1 >1 - 5	½ tablet (oblong white) 1 tablet (oblong white)	
>5 - 25 >25 - 50		1 tablet (round, white) 2 tablets (round, white)